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The Infertility Industry:
Inspiring Technology Gives Birth to
Complex Moral Uncertainties

Megan Rachelle Leef

Abstract

Assisted reproductive technologies (ART) are rapidly advancing, permitting more couples and individuals to overcome their infertility. These advances, taking place largely outside the reach or view of government regulation or oversight, create numerous important consequences that raise serious ethical considerations. There is a need for consumer protection for infertile couples, as well as the assurance of the safety and efficacy of techniques and donated human cellular materials. Most fundamentally the moral questions raised by the techniques and their consequences must be addressed. The legal status of embryos, the many problems that arise from multiple fetus pregnancies that result from over-implantation of embryos, the non-therapeutic genetic screening that the technology permits, and the ever-increasing maternal age all raise fundamental ethical dilemmas. These dilemmas are not being resolved because any discussion or resolution treads close to the emotional and politically charged politics of abortion. This paper highlights the various consequences of ART, identifies the ethical consequences, and discusses the proper forum for their possible resolution.

The Infertility Industry:
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I. Introduction

On July 6, 2001, the FDA sent a warning letter to fertility researchers announcing that the agency had regulatory authority over a controversial treatment that involves “the mixing of male and female genetic material in any way other than the straightforward union of sperm and egg.”¹ It informed researchers that use of “such genetically manipulated cells... in humans constitutes a clinical investigation and requires submission of an Investigational New Drug Application (IND) to FDA.”² This letter followed reports of fetal abnormalities from a procedure in which an infertile woman’s egg was mixed “not only with her husband’s sperm but also with parts of a younger woman’s egg, creating children with three genetic parents - - a biological first.”³ The agency’s assertion of authority was an example of increased efforts in the 1990s to clarify its jurisdiction over human cellular and tissue-based products, including those used for reproduction.⁴

¹Rick Weiss, *FDA to Regulate Certain Fertilization Procedures*, WASH. POST, July 11, 2001, A2.

²Letter to Sponsors/Researchers – Human Cells Used In Therapy Involving the Transfer of Genetic Material by Means other than the Union of Gamete Nuclei, July 6, 2001, available at <http://www.fda.gov/cber/ltr/cytotrans070601.htm>.

³Rick Weiss, *Pioneering Fertility Technique Resulted in Abnormal Fetuses; Team Failed to Disclose Genetic Disorder in Science Report*, WASH. POST, May 18, 2001, A3.

⁴See Tissue Action Plan – Reinventing the Regulation of Human Tissue, February 1997, available at <http://www.fda.gov/cber/tissue/rego.htm>

The primary articulated justification for this authority is the prevention of the transmission of communicable diseases under § 361 of the Public Health Service Act.⁵ Until recent attempts to exercise some jurisdiction over the safety and effectiveness of industry practices, the fertility industry has operated largely outside the scope of regulation or government oversight, leaving self-regulation as the only possible check on the practices and ethics of a rapidly growing industry.

The action of the Food and Drug Administration highlights the importance of the ethical and policy issues raised by scientific progress in reproductive technologies. It also raises significant questions about the proper role of the FDA in responding to controversial scientific developments. This paper endeavors to highlight and analyze some of the consequences of medical advances in the field of assisted reproductive technologies (ART), and the proper government reaction to these consequences. It seems that “the fertility industry often rides the line between benevolent heroism in the service of infertile couples and fee-for-service experimentalism in which patients desperate to become pregnant are easily drawn to unproven and often expensive treatments.”⁶

The rapid pace of technological advance in fertility treatments raises a host of issues which society must confront. The vulnerability of consumers of ART raises the danger of exploitation and necessitates some kind of consumer protection. Further, the technologies and procedures themselves must be safe and effective for use. Finally, there are substantial and controversial moral questions about the ethics of certain procedures and the consequences of industry practices. Some of the consequences that raise ethical problems include: (1) the storage and destruction of embryos, (2) the multiple fetal pregnancies that result from the implantation of multiple embryos and selective reduction of those pregnancies, (3) the issue of non-therapeutic genetic screening, and (4) the increasing availability of reproductive technologies to older women who are past the traditional age of childbearing. Governmental actors have been slow to address these potential problems, and the result has been an industry that operates largely outside the scope of government oversight.

⁵24 U.S.C. 264.

⁶R. Weiss, *supra* note 3.

Responding to pressure in the wake of various fertility scandals, as well as the intense feelings about recent cloning efforts, the federal government has cautiously entered the fray of regulating fertility clinics and practices. Much of the regulation, however, fails to squarely confront or resolve the thorny ethical issues that these procedures raise. Additionally, there are legitimate and substantial questions about whether the FDA has the authority it claims to undertake its recent regulatory programs, and whether such regulatory leadership unnecessarily obstructs public debate and political resolution of these controversial issues.

II. Background on Infertility and Assisted Reproductive Technology

The increasing availability and success of various fertility treatments currently hold out promise to the many childless couples in the United States who desire a biologically related child. Infertility affects an estimated 6.1 million people in the United States, approximately ten percent of the reproductive age population.⁷ The American Society for Reproductive Medicine defines infertility as “a disease of the reproductive system that impairs one of the body’s most basic function: the conception of children.”⁸ Infertility has many causes, both male and female. In men, low sperm count is frequently the cause of fertility problems, while the causes of female factor infertility are more varied. Some causes can be blockage of the fallopian tubes as a result of endometriosis or use of intra-uterine device (IUD), infrequent ovulation, as well as age-related

⁷“Quick Facts About Infertility,” American Society for Reproductive Medicine, available at <http://www.asrm.org/patients/faqs.html>. See also 1999 ART Report, available at <http://www.cdc.gov/nccdphp/drh/ART99/99nation.htm>, page 3. “Of 60 million women of reproductive age in 1995, about 1.2 million, or 2%, has an infertility-related medical appointment within the previous year.... Additionally 7% of married couples in which the woman was of reproductive age reported that they had not used contraception for 12 months and the woman had not become pregnant.”

⁸ASRM report.

diminution of the quality and fertility of a woman's eggs.⁹ These various causes contribute to a serious problem of infertility for millions of Americans, which has dramatic emotion and economic consequences on those infertile couples and the greater economy.

Most cases of infertility are treated conventionally using drug treatment or surgical repair of reproductive organs. Assisted reproductive technology (ART) is used to treat infertility that is not successfully addressed by conventional drug and surgical therapies. There are three main types of ART: in vitro fertilization (IVF),¹⁰ gamete intrafallopian transfer (GIFT),¹¹ and zygote intrafallopian transfer (ZIFT).¹² The Centers for Disease Control and Prevention (CDC) estimates that ART accounts for approximately 0.8% of total U.S. births.¹³ The use of ART is on the rise in the United States as the technology improves and more couples turn to medical assistance to deal with infertility. In 1999, the most recent year for which there is available data, 86,822 cycles of ART treatment were initiated.¹⁴ In comparison, in 1994 there were 39,390 ART procedures performed,¹⁵ and in 1995 there were 59,142.¹⁶ According to the ASRM, "[m]ore than 30,000 babies were born in 1999 as the result of assisted reproductive technology (ART)."¹⁷ As the use of ART increases, and as more couples turn to medical technology to bear children, the consequences will become harder for the public and the government to ignore.

⁹See generally, Keith Alan Byers, *Infertility and In Vitro Fertilization, A Growing Need for Consumer-Oriented Regulation of the In Vitro Fertilization Industry*, 18 J. LEGAL MED. 265, 268-69 (1997).

¹⁰According to the CDC, IVF involves extracting a woman's eggs, fertilizing the eggs in a laboratory, and then transferring the resulting embryo(s) into the woman's uterus through the cervix.

¹¹According to the CDC, GIFT involves using a fiber-optic instrument called a laparoscope to guide the transfer of unfertilized eggs and sperm (gametes) into the woman's fallopian tubes through small incisions in her abdomen.

¹²ZIFT involves fertilizing a woman's eggs in a laboratory and then using a laparoscope to guide the transfer of the fertilized eggs (zygotes) into her fallopian tubes.

¹³1999 ART Report, available at <http://www.cdc.gov/nccdphp/drh/ART99/99nation.htm>, page 13.

¹⁴See Centers for Disease Control and Prevention, 1999 Assisted Reproductive Technology Success Rates, available at <http://www.cdc.gov/nccdphp/drh/ART99/index99.htm>.

¹⁵See Society for Assisted Reproductive Technology & The American Society for Reproductive Medicine, Assisted Reproductive Technology in the United States and Canada: 1994 Results Generated From the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, 66 Fertility & Sterility 697 (1996).

¹⁶See Centers for Disease Control and Prevention, 1995 Assisted Reproductive Technology Success Rates, available at http://www.cdc.gov/nccdphp/drh/archive/arts/art_type.htm.

¹⁷ASRM Press Release, Dec. 14, 2001, available at <http://www.asrm.org/Media/Press/99art.html>.

III.

The increasing availability of technologically innovative fertility treatments creates a host of difficult problems. First, the asymmetry of information between financially motivated doctors and emotionally vulnerable patients necessitates some form of consumer protection. Second, there must be a way to make sure that these procedures are safe and effective for both the recipient of ART and the future children created by the technology. Finally, there are myriad thorny ethical issues that these technologies implicate, which have yet to be squarely address by policy-makers.

A. *There is a Need for Consumer Protection in the Fertility Industry.*

The ease with which clinics can misrepresent their success rates raises the possibility of fraud upon infertile couples. “In the ‘Wild Wild West’ of ART, doctors fraudulently impregnate their patients, fertility researchers use their patients’ genetic samples without valid consent, and clinics fail to safely screen potential donors.”¹⁸

i. Recipients. Even absent fraud, infertile couples need help in comparing clinics in order to make an educated decision. With treatment costs in the thousands of dollars, few insurance programs covering this treatment option, and the frequency of interstate travel for fertility treatment, the federal government has an important role to play in ensuring accuracy in advertising and promotion of clinical services. Fertility clinics can abuse their patients’ trust in a variety of ways, from inflating their success rates to substituting human cellular

¹⁸Alexander H. Hecht, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 Hous. J. Health L. & Pol’y 227 (2001).

components from different donors (sperm and eggs) to increase the likelihood of success. “Many infertility practitioners are becoming more business-oriented than medically-oriented. This field of medicine... has become a billion-dollar annual business.”¹⁹ Opportunities abound to mislead people desperate to become parents.

Clinics have a strong competitive interest in producing high success rates relative to other clinics, and this competitive pressure can lead clinics and practitioners to sacrifice honest disclosure as well as patient safety. Though the industry is represented by the American Society for Reproductive Medicine (ASRM), many clinics do not comply with ASRM’s guidelines, particularly in responding to patient requests for implantation of more embryos, which boosts the chances of successful pregnancy but also can lead to multiple births or selective pregnancy reduction.²⁰ “Reproductive doctors fail to follow the guidelines because the more implants they use, the greater the success rates for the procedure.... Monetary goals illustrate why the reproductive doctors do not follow standards dictating maximum numbers of implants. Fundamentally, it would be bad for business.”²¹

ii. Donors. Donation of cellular material also implicates the need for consumer protection for donors from exploitation. Donation of cellular material is not exclusively for use by older patients, but the increasing age of women hoping to become pregnant leads to greater demand for egg donation. “Because research indicates that the ability to conceive naturally or to successfully carry an embryo to term decreases with age, egg donation seems to be an effective means of providing an older woman with the opportunity to give

¹⁹B. Jason Erb, *Deconstructing the Human Egg: The FDA’s Regulation of Scientifically Created Babies*, 5 ROGER WILLIAMS U.L. REV. 273, 282 (1999).

²⁰For the ethical problems of selective reduction and multiple fetus pregnancies, see discussion *infra* Part III(C)(ii), pages 19-21.

²¹Erb, *supra* note 19, at 288-89.

birth....”²² However, the payment of large sums of money to men and women for sperm and egg donation raises important questions. “Although the sale of human parts is prohibited by both federal and state statute, fertility specialists operate within a legal loophole, whereby the procedure is defined as a donation and not as a sale. The money paid [to egg donors] is merely compensation for her ‘time and trouble.’ As a result little consumer protection exists in this area of medical practice.”²³

“With the number of egg transplants—each usually involving multiple eggs—surpassing 7,000 in 1998 and doubling every two to three years, the fierce competition has forced brokers to offer ever larger financial enticements.”²⁴ Donors deserve protection from unscrupulous clinics eager to procure cellular material for their patients. Critics of the egg donation market, such as Harvard law professor Elizabeth Bartholet argue that it is a violation of human dignity. “I think it’s deeply problematic to encourage women, for money, to sell their reproductive capacities and their parenting rights, both of which are at issue in egg sale transactions.”²⁵ But the American Society for Reproductive Medicine maintains that monetary payment to egg donors should be viewed in the “same way federal and state laws view compensation to organ and tissue donors: It is for the work the donor goes through so that an organ or tissue can be retrieved, not for the organ or tissue itself.”²⁶

However, critics cite the relative youth of the targeted donors, who are often college students, as well as the lure of sums of money ranging from \$5000 to \$10,000. “The money is particularly alluring to women attending top private universities, which now cost \$32,000 to \$35,000 a year.”²⁷ “The ethics of soliciting eggs from undergraduate women becomes particularly questionable when one considers the ages most of these

²²Sherri A. Jayson, “*Loving Infertile Couple Seeks Woman Age 18-31 to Help Have Baby. \$6500 Plus Expenses and a Gift*”: *Should We Regulate the Use of Assisted Reproductive Technologies by Older Women?*, 11 ALB. L. J. SCI. & TECH. 287, 304 (2001).

²³*Id.* at 328.

²⁴Kenneth Weiss, *The Egg Brokers*, L.A. TIMES, March 27, 2001, at A1.

²⁵*Fertility Medicine: Legal, ethical issues remain in egg donation*, GENOMICS AND GENETICS WEEKLY, Mar. 15, 2002, at 9. (2002 WL 9236984).

²⁶*Id.*

²⁷K. Weiss, *supra* note 24.

firms target: 18 to 22.”²⁸ One controversial ad placed in college newspapers around the country read: “Egg Donor Needed. Large Financial Incentive. Intelligent, athletic egg donor needed for loving family. You must be at least 5’10. Have a 1400+ SAT score. Possess no major family medical issues. \$50,000. Free medical screening. All Expenses Paid.”²⁹ While most fees are between \$3000 and \$5000, “ ‘It has moved from a gentlemanly marketplace of insiders to a more open, flamboyant marketplace,’ said Arthur Caplan, director of the University of Pennsylvania’s Center for Bioethics. ‘There is not much difference between those ads and what goes on with prize breeding of animals.’ ”³⁰

This market for eggs continues, largely unregulated by state or federal authorities. States have different rules regarding egg donation, requiring more or less secrecy. California, which has been on the cutting edge of fertility treatments, also has a very permissive regulatory scheme that allows. “California has a higher concentration of egg brokers than anywhere else in the nation, a phenomenon attributable to a combination of factors—from pioneering efforts in fertility treatments to an anything-goes culture.... Unlike East Coast agencies, which swaddle donors in secrecy, California brokers allow infertile couples to choose their donors—scrutinize their pictures, learn their family histories, even take them to dinner.”³¹ Whether the donors need protection from exploitation is a matter of debate, but as yet no political or ethical consensus has been reached.

The need for consumer protection in the ART and related markets is clear. Potential parents, the donors of the eggs and sperm, and the children created with the technology all deserve some protection from the enormous financial pressure which makes the fertility clinics themselves suspect as the ideal enforcers of ethical norms.

²⁸Matt Brophy, *Egg donation firms exploit college women*, UNIVERSITY WIRE, Mar. 7, 2002, (2002 WL 14816172).

²⁹K. Weiss, *supra* note 24.

³⁰*Id.*

³¹*Id.*

B. Safety and Efficacy Must be Assured for Recipients and Offspring.

Any ART process that includes the use of donated human cellular or tissue material raises important health and safety concerns, both for recipients of the tissue and the potential future offspring. The safety concerns include the transmission of communicable diseases, such as AIDS and hepatitis to the recipients of tissue and cellular materials. There are additional health and safety concerns for potential offspring; the long-term effect of these technologies are unknown and have not been verified or tested prior to their use.

i. Recipients. As with any cellular donation, there is a risk of transmission of communicable diseases such as HIV/AIDS. Indeed, President William Clinton recognized the need for safety regulation of human tissue donation in the *Tissue Action Plan*³² that was issued in February of 1997. This plan proposed a new approach to the regulation of tissue, the goals of which were

1) preventing unwitting use of contaminated tissues with the potential for transmitting infectious diseases such as AIDS and hepatitis; 2) preventing improper handling or processing that might contaminate or damage tissues; 3) ensuring that clinical safety and effectiveness is demonstrated for tissues that are highly processed, are used for non-natural purposes, are combined with non-tissue components, or are used for metabolic purposes.³³

Thus the federal government recognized and articulated its concerns about protecting individuals receiving donated tissue from disease and ensuring the safety and effectiveness of those donations. The “overarching public health and regulatory concerns” included preventing the transmission of communicable diseases, ensuring clinical safety and effectiveness, and assessing what labeling and promotion were necessary and permissible.³⁴

The dangers posed by donated tissue led the FDA to promulgate a proposed rule in 1999 requiring screening and testing of donors of cells and tissue “for risk factors for and clinical evidence of relevant communicable

³² *Tissue Action Plan – Reinventing the Regulation of Human Tissue*, February 1997, available at <http://www.fda.gov/cber/tissue/rego.htm>

³⁴ *Id.*

diseases.... [to] improve protection of public health and increase public confidence in new technologies....”³⁵

In 2001 the FDA issued a final rule requiring “[e]stablishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissues intended for transplantation... [to register] with the agency” and provide information to the FDA about their tissue and cell activities.³⁶ In response to the inclusion of reproductive cells and tissue in the new rule, the FDA stated that “[c]urrently, FDA does not have regulations in place to address the infectious disease risk of donating, processing, and storing reproductive cells and tissue. Because there has been no registration or listing requirement, we have not had accurate information about the industry.”³⁷

The dangers from the transmission of communicable diseases by human tissue recently prompted the FDA to issue regulations designed to ensure the safety of the nation’s tissue supply by requiring screening for diseases, as well as establishment registration and listing.³⁸

ii. Offspring. In addition to protecting the recipients of cellular material donated for reproductive purposes, it should be imperative that the children conceived using these novel techniques are protected. The procedures should be safe and effective not just for the potential parents, but their desired offspring. The Washington Post reported that a pioneering fertility technique, mentioned above, involving the mixing of parts of a younger woman’s egg with an older woman’s egg and her husband’s sperm, resulted in abnormal fetuses.³⁹

Two of seventeen fetuses created using the technique had Turner’s syndrome, a rare disorder in which a

³⁵*Suitability Determination for Donors of Human Cellular and Tissue-Based Products*, 64 Fed. Reg. 52,696 (proposed Sept. 30, 1999).

³⁶*Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 66 Fed. Reg. 5447 (to be codified at 21 C.F.R. pt. 207, 807, and 1271) (issued January 19, 2001).

³⁷*Id.* at 5452.

³⁸*See Suitability Determination for Donors of Human Cellular and Tissue-Based Products*, 64 Fed. Reg. 52,696 (proposed Sept. 30, 1999); *Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 66 Fed. Reg. 5447 (to be codified at 21 C.F.R. pt. 207, 807, and 1271) (issued January 19, 2001).

³⁹R. Weiss, *supra* note 3.

chromosome is missing.⁴⁰ These results led to miscarriage in one pregnancy, and led the scientists to abort the other developing fetus that had Turner's. These results were not included in the scientists' published report, which concluded there was no reason to believe the technique was harmful to fetuses or babies.⁴¹

Time Magazine reported that the New England Journal of Medicine published two reports that conventional wisdom about the safety of ART for future offspring "may be wrong."⁴² In the first study cited by Time, doctors in Britain and Australia reportedly found an increased risk of major birth defects in infants conceived using both the traditional test-tube methods and a more invasive technique, in which sperm is injected into the egg. Specifically, these babies had an 8.6% risk of major birth defects, "including heart and kidney abnormalities, cleft palate and undescended testicles," which is significantly higher than the 4.2% rate typical in the greater population.

The second study, conducted by the CDC, reported that babies conceived using ART had 2.6 times the risk of low or very low birth weight. Low birth weight is correlated to myriad problems including cognition problems. Time reported that the researchers concede that the findings are controversial, 'and they aren't going to be the final word on the issue. But parents should be aware of the controversy.' "⁴³ This research emphasizes the importance of assuring safety and efficacy, an issue which has been taken for granted or largely been ignored in the fertility industry.

While the fertility industry and the broader medical community has generally taken for granted the long-term safety of the technologies, there has been no verification of the long-term effects these technologies have on future children.

⁴⁰The rate of incidence, two out of seventeen, is at least seven to eight times what experts deem normal. See R. Weiss, *supra* note 3.

⁴¹*Id.*

⁴²Michael Lemonick, *Risky Business?; Do infertility treatments damage babies' genes? Doctors used to think not. Now they are not so sure*, TIME, Mar. 18, 2002, 68.

⁴³*Id.*

C. ART Raises Many Complex Ethical Problems.

There are a variety of ethical problems created by the increased success and use of ART. These include the necessity of addressing the legal status of embryos that are created in the ART process; the risks and consequences of multiple fetus pregnancies, including selective reduction; the related issue of gender selection; finally, a major ethical question raised by ART is the rising age of potential mothers.

i. Frozen Embryos' Ethical and Legal Status. Various technological innovations have fundamentally changed the possible circumstances under which conception can take place. As a result, the ART industry necessarily produces varied ethical questions surrounding the creation, preservation, storage and destruction of embryos. "Because IVF procedures may produce more fertilized eggs than can be implanted safely for gestation, a couple may leave unused pre-embryos at the IVF clinic to be frozen and stored. It has been estimated that tens of thousands of pre-embryos are frozen each year."⁴⁴ In fact, it is unclear whether embryos are property of the donors whose sperm and egg created them, or if there are fetal rights independent of the donors' wishes. This lack of clarity collides with the highly inflammatory abortion debate because any treatment of embryos as entities other than property is seen as threatening women's dominion over the voluntary termination of pregnancy. The status of embryos created for ART purposes also runs into the current debate over stem cell research. The numerous frozen embryos stored in fertility clinics around the country have also become part of the heated argument over research using stem cells, which are extracted from human embryos, and result in the destruction of the embryo.

The human embryo is viewed by many as the beginning of human life, deserving of the legal and moral respect due any human being. "It is important to recognize also that research involving human embryos outside the womb—such as embryos produced in the laboratory by in vitro fertilization (IVF) or cloning—has

⁴⁴Helene S. Shapo, *Frozen Pre-Embryos and the Right to Change One's Mind*, 12 DUKE J. COMP. & INT'L L. 75, 76 (2002)

never received federal funding.”⁴⁵ The approach of the federal government has been largely laissez-faire, permitting clinics to create, use and store embryos as they see fit. This atmosphere leads fertility clinics to create more embryos than are immediately needed. “Costly treatments prompt doctors and couples to create more embryos than they need in a single implantation, so the extras are frozen.”⁴⁶ The uncertain legal and ethical status of embryos, and the attendant political fervor, dramatically impacts not just the ART industry, but myriad scientific developments, from stem cell research to cloning. “But the debate over stem-cell research ignores more fundamental questions about embryos themselves. No one really knows how many frozen embryos exist or how they are being used. No government agency tracks or regulates the creation or disposition of embryos.”⁴⁷

The legal status of embryos is squarely presented in the context of divorcing couples litigating the fate of embryos created for ART when the marriage was in tact. “The issue of frozen preembryos in divorce cases raises constitutional, property and contract issues which courts will increasingly have to address.”⁴⁸ There is no mention in the case law, most of the literature, and even in infertility practices, of any rights of the embryos in question. “One prominent medical ethicist, George J. Annas, suggests that in a typical scenario, decision-making standards center on the sperm donor or infertile couple’s best interests, rather than those of the child.”⁴⁹ This is probably because courts view debate over the legal status of embryos as entities with enforceable rights as foreclosed by the Supreme Court’s abortion jurisprudence, represented in *Roe v.*

*Wade*⁵⁰ and *Planned Parenthood of Southeastern Pennsylvania v. Casey*⁵¹.

⁴⁵ *On Human Embryos and Medical Research: An Appeal for Ethically Responsible Science and Public Policy*, 16 ISS. L. & MED. 261, 263 (2001).

⁴⁶ Nancy Parelo, *Frozen Emrbyos, Heated Debate, Couples, Doctors Face Ethical Issues*, THE RECORD, BERGEN COUNTY, NJ, Aug. 20, 2001, at A1.

⁴⁷ *Id.*

⁴⁸ Thomas D. Arado, *Frozen Embryos and Divorce: Technological Marvel Meets The Human Condition*, N. ILL. UNIV. L. REV. 241 (2001).

⁴⁹ Hecht, *supra* note 18 (citing George J. Annas, *Fertility Clinics Hardly Letter-Perfect*, BOSTON GLOBE, Nov. 30, 1997, at D1 (asserting that in most fertility clinics, desire and money serve as surrogates for child welfare)).

⁵⁰ 409 U.S. 817 (1972).

⁵¹ 505 U.S. 833 (1992).

Though the reasoning is not uniform, “[i]n the United States, pre-embryo custody disputes have resulted in at least five reported cases in which courts have awarded the pre- embryos to the party opposing implantation.”⁵² In *Davis v. Davis*,⁵³ the Tennessee Supreme Court held that “in the absence of a prior agreement which would govern disposition, the party wishing to avoid procreation should prevail, assuming the other party had ‘a reasonable possibility of achieving parenthood by means other than use of the preembryos in question.’ ”⁵⁴

In *Kass v. Kass*,⁵⁵ the court held on nearly identical facts that the consent forms, embodying the pre-fertilization intent of the parties, controlled the disposition of five contested frozen embryos that the ex-wife sought to have implanted over the objection of the biological father. *Kass* seemed to approve of a contract approach to the resolution of the status of embryos. However, the notion that the fate of embryos is an enforceable contract term was rejected in *A.Z. v. B.Z.*⁵⁶ In that case, “the court held that the contract at issue, which would have given the pre-embryos to the party wishing to bring them to term, was unenforceable as against public policy. To hold otherwise, the court decided, would amount to judicially enforced procreation.”⁵⁷

The New Jersey Supreme Court has also offered guidance as to the construction of contracts purporting to settle the question of embryo disposition. Recently, in *J.B. v. M.B.*,⁵⁸ the court suggested “that disposition agreements entered into at the time IVF was commenced are enforceable but that if after a divorce the parties disagree as to disposition, then the party wishing to avoid procreation should ordinarily prevail.”⁵⁹ Though not identical in their reasoning, the cases treat the legal status of embryos as a property and creation interest

⁵²Shapo, *supra* note 44, at 76 (citing *A.Z. v. B.Z.*, 725 N.E.2d 1051 (Mass. 2000); *J.B. v. M.B.*, 751 A.2d 613 (N.J. Super. Ct. App. Div. 2000), *aff’d in part*, 2001 WL 909294 (N.J. Aug. 14, 2001); *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998); *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1991); *Litowitz v. Litowitz*, 10 P.3d 1086 (Wash. 2000)).

⁵³842 S.W.2d 588 (1992).

⁵⁴842 S.W.2d at 604.

⁵⁵No. 19658189, 1995 WL 110368 (N.Y. Sup. Ct., Jan. 18, 1995).

⁵⁶725 N.E.2d 1051 (Mass. 2000).

⁵⁷725 N.E.2d at 1057-58.

⁵⁸783 A.2d 707 (N.J. 2001).

⁵⁹783 A.2d at 719.

of the individuals who contributed the constituent biological components, with public policy considerations entering the discussion only with respect to the right of individuals to control their parental destiny.

Some states have attempted to legislate responses to these unique situations. For example, Florida law requires couples undergoing any ART procedure to enter into a written agreement providing for the disposition of eggs, sperm, and embryos in the event of divorce, death, or “other unforeseen circumstance[s].”⁶⁰ Though required resolution by contract may not resolve all situations, it represents a recognition by the state legislature of the extraordinary questions that arise out from ART. Louisiana took a more definitive approach to resolving the status of embryos in a 1986 law that declares an in vitro fertilized human ovum to be a “juridical person” that could only be disposed of through implantation.⁶¹ Thus, “if the IVF patients ‘fail to express their identity’ or renounce their parental rights, then the physician is deemed the embryo’s temporary guardian until adoptive implantation can occur.”⁶²

Additionally, ART clinics themselves may attempt to prevent such future disputes by requiring patients to state their decisions about extra embryos in advance. Included in many forms required by ART clinics is a choice about “what should be done with their pre-embryos in a variety of future situations, including divorce. The choices include destroying the pre-embryos, giving them to the clinic for research, donating them to another couple, and releasing them to one of the parties.”⁶³

Some couples do avail themselves of the option of donating their frozen embryos to other couples struggling with infertility. This option is the ideal manner by which to dispose of frozen embryos that are unlikely to be used by the biological parents. It avoids the ethical problems of destruction or research carried out on the embryos, while also giving infertile couples a chance to become parents. There is a California organization

⁶⁰FLA. STAT. ANN. § 742.17 (West 1997).

⁶¹LA. REV. STAT. ANN. §§ 9:123, 9:126 (West 1991).

⁶²Judith Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, at 624 (1997).

⁶³Shapo, *supra* note 44, at 80.

called Snowflake is trying to encourage more couples to place their embryos for ‘adoption.’ Adoption of embryos is different from donation because Snowflake allows the parents of the embryos to choose their potential child’s future family; donation leaves the fate of the embryos to the doctors at the fertility clinic. “The program, which is part of a traditional adoption agency called Nightlight Christian Adoptions, has so far matched 35 genetic families with 28 adoptive families, resulting in eight babies, with six more on the way, agency representatives said.”⁶⁴ Unfortunately, some say embryo adoption or donation is a tough sell. It’s my baby that somebody else will have, said [one mother], who has one child from in-vitro fertilization and four frozen embryos.”⁶⁵ Currently there is no governmental policy favoring donation of embryos for adoption by other infertile couples. Furthermore, there is no tracking of the number of donations by private or government bodies. Trying to understand some of the broader ethical issues raised by ART, a New Jersey newspaper investigated local donation practices. “In 1998, 16 New Jersey fertility clinics reported implanting just 99 donated frozen embryos, or 2 percent of more than 3,700 in-vitro fertilization procedures performed.... Most clinics did not implant any donated frozen embryos. The two largest, Cooper Center for In Vitro Fertilization and St. Barnabas Medical Center, reported the most, with 50 and 22, respectively.”⁶⁶

Snowflake charges \$4500 for its adoption services, but it seems desirable for a non-profit or governmental organization to attempt to effectuate embryo donation or adoption.⁶⁷ Such a policy might decrease the number of embryos destroyed or over whom the custody/ownership is litigated. Furthermore, it would provide other infertile couples with an alternative to the costly harvesting procedures that might prevent them from seeking ART procedures in the first place.

At the root of many of these legal problems lies the basic ethical uncertainty over the moral status of a human

⁶⁴Parello, *supra* note 46.

⁶⁵*Id.*

⁶⁶*Id.*

⁶⁷See Snowflake Organization website, available at <http://www.snowflake.org>.

embryo. A human embryo represents to many the beginning of human life, deserving of respect and protection from harm, exploitation and destruction. Because of ART, the human embryo also represents a commodity of sorts, used to enable childbearing and increase success rates. The creation of embryos for implantation frequently results in superfluous embryos, the disposition of which raises thorny ethical questions. Political resolution seems unlikely given the intensity of the abortion debate and the seeming foreclosure of most legislative action on abortion by the Supreme Court. The political route being unavailable, the impetus for discussion and resolution of the status of embryos used in ART is missing. For now, fertility clinics can largely do what is expedient, governed only by the application of state contract and tort law for wrongdoing.

ii. Multiple Fetus Pregnancies. Because of the pressure to achieve high success rates, represented in pregnancies and live births, ART clinical decision making “is heavily focused on maximizing a woman’s chances of becoming pregnant. One common practice that aims to increase the likelihood of pregnancy is to transfer multiple embryos (often more than 3) into the uterine cavity. This treatment approach also presents an important drawback, however, because it increases the risk for multiple birth.”⁶⁸ Approximately 71% of ART cycles that progressed to the embryo transfer stage in 1999 involved the transfer of three or more embryos. 36% involved the transfer of four or more and nearly 14% involved the transfer of five or more embryos.⁶⁹ This raises important health and ethical concerns because “transferring multiple embryos also poses a risk of having a multiple-infant birth. Multiple infant births cause concern because of the additional health risks they create for both mothers and infants.”⁷⁰

The health risks to mother and child are substantial. “Fetal risks of multiple gestation include an increased chance of miscarriage, birth defects, premature birth, and the mental and/or physical problems that can result

⁶⁸Live-Birth Rates and Multiple-Birth Risk Using In Vitro Fertilization. JAMA. 1999; 282:1832-1838available at <http://jama.ama-assn.org/issues/v282n19/ffull/joc90673.html>.

⁶⁹CDC Report, *supra* note 13, at 34.

⁷⁰*Id.* at 35.

from a premature delivery.... Maternal risks due to multiple gestation include premature labor, premature delivery, pregnancy-induced high blood pressure or pre-eclampsia (toxemia), diabetes, and vaginal/uterine hemorrhage.”⁷¹ Multifetal pregnancies occur at a much greater frequency using ART than do in the general population of the United States. Overall, in 1999, 37% of ART pregnancies included more than one fetus as compared to 3% in the general population.⁷² This raises serious ethical considerations that merit discussion and resolution.

(A) Selective Reduction. Because so many ART pregnancies include more than one fetus, doctors sometimes desire to reduce the number of fetuses. Multifetal pregnancies may be reduced to twins or singletons by the time of birth, either naturally (e.g., fetal death), or “[p]regnancies with multiple fetuses can be associated with the possibility of multifetal reduction.”⁷³ Multifetal reduction is a medical term for what some call “selective abortion;” whatever term is used, the procedure involves reducing the number of developing fetuses in a mother’s womb through some form of induced abortion. “Multifetal pregnancy reduction is usually performed between nine and 12 weeks gestation, but it has been performed as late as 24 weeks gestation. The procedure is most successful when performed early in the pregnancy. It is done on an outpatient basis by inserting a needle guided by ultrasound either through the abdomen or vagina to inject potassium chloride into the fetus.”⁷⁴ The injection of potassium chloride results in fetal death. The term abortion is not used by the medical community because the stated intention in cases of multifetal pregnancy reduction is that the pregnancy continue, but with fewer fetuses.⁷⁵ In the case of high-order pregnancies (defined as triplets

⁷¹American Society for Reproductive Medicine, *FACT SHEET: Multiple Gestation and Multifetal Pregnancy Reduction*, available at <http://www.americaninfertility.org/asrm/multiple.html>

⁷²CDC Report, *supra* note 13, at 20.

⁷³*Id.* at 35.

⁷⁴American Society for Reproductive Medicine, *FACT SHEET: Multiple Gestation and Multifetal Pregnancy Reduction*, available at <http://www.americaninfertility.org/asrm/multiple.html>

⁷⁵See The FIGO Committee for the Study of Ethical Aspects of Human Reproduction, *Recommendations on Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Study of Ethical Aspects of Human Reproduction*, “Selective Reduction of Multiple Pregnancy,” July 1997, available at <http://www.md.huji.ac.il/figo/figo8.htm>

or more) “it may be considered ethically less unacceptable to selectively reduce the number of fetuses than to do nothing. It is very important that such selective reduction should not be considered as an alternative to very careful monitoring of infertility treatment.”⁷⁶

The ethical problems raised by selective pregnancy reduction in multiple fetus pregnancies from ART are complicated and serious. Is it ethical for doctors to knowingly increase their patients’ risk of multiple fetus pregnancies by implanting numerous embryos and then eliminating additional fetuses which result? The propriety of the practice also necessarily implicates the broader, unresolved ethical debate about the morality of abortion in general; namely whether fetuses are persons deserving of protection from harm, exploitation, and destruction.⁷⁷ The ethical questions are complicated by the doctors’ pecuniary interest in achieving higher success rates than competing ART clinics and doctors. Because implantation of multiple embryos increases the odds of a live birth for patients, doctors have an incentive to implant more embryos and deal with additional fetuses by selective reduction rather than calculated and careful ART treatment.

iii. Non-Therapeutic Genetic Screening. The combination of assisted reproductive technologies and genetic screening techniques create the very real possibility of non-therapeutic genetic screening for a variety of factors, like gender and eye color. “While Congress has considered regulating genetic information or reproductive technology in other contexts, legislators have not yet proposed legislation to regulate the use of PGS for nontherapeutic purposes—that is, for purposes other than to insure the absence of genetic disease.”⁷⁸ The use of preimplantation screening creates serious ethical problems which may need to be resolved by regulation. “Scientists, ethicists, and the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research have advised against using fetal diagnosis for sex selection because

⁷⁶*Id.*

⁷⁷The morality of abortion is a perennial political and legal debate which exceeds the scope of this paper. It merits notation however, as representative of the many serious ethical dilemmas raised by ART, and their lack of meaningful political resolution.

⁷⁸Vicki G. Norton, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation*, 41 U.C.L.A. L. REV. 1581, 1584 (1994).

it offends notions of gender equality. ... In addition, prenatal diagnosis and selective abortion may lead to parents viewing children as a means to an end, rather than as children to be accepted unconditionally.”⁷⁹

In the context of ART, there are two times at which non-therapeutic selection becomes possible: pre-implantation and post-implantation. “Selective pregnancy reduction, a medical procedure used in multiple pregnancies, has been used to select the gender of the fetus brought to birth. The euphemistic selective pregnancy reduction can more honestly and accurately be labeled sex or gender selection abortion. There is an intuitive disfavor accompanying this mode of gender selection.”⁸⁰

There are also three types of genetic characteristics which might serve as the basis for concern about the “discriminatory effects of genetic screening: cosmetic traits, which relate to the appearance of the individual; performance traits, which relate to an individual’s talents and abilities; and therapeutic genetic traits, which relate to severe health problems.”⁸¹ Intuitively, screening for therapeutic reasons seems less objectionable, because of the avoidance of tragic and burdensome genetic diseases and the creation of healthy offspring. The other two types of genetic screening permit selection of desired traits which “may encourage parents to begin thinking of children as commodities.”⁸² However, there are still strong moral objections to even therapeutic screening, based on the sanctity of any human life, and the fear of a eugenics movement that will, through selective genetic screening, facilitate an elite class of people free from any and all genetic abnormality.

There appears to be little moral distinction between pre-implantation and post-implantation nontherapeutic genetic screening. New technology might render the use of selective reduction of existing fetuses obsolete, as preimplantation screening becomes easier. Additionally, scientists are increasingly able to “Scientists in 1996 published articles on the availability of a technique to separate sperm of mammals into those carrying an X chromosome and those carrying a Y chromosome. In February of 1998, a group of Spanish scientists

⁷⁹*Id.* at 1604.

⁸⁰Weldon E. Havins, *The Ever-Widening Gap Between the Science of Artificial Reproductive Technology and the Laws which Govern that Technology*, 48 DEPAUL L. REV. 825, 842-43 (1999).

⁸¹Norton, *supra* note 78, at 1607.

⁸²*Id.* at 1609.

demonstrated that the fluorescent in-situ hybridization (FISH) technique would produce 80 to 90% purity for X spermatozoa and 60 to 70% for Y spermatozoa. This remarkable advance resulted in the Genetics and IVF Institute, based in Fairfax, Virginia, reporting an 85% success rate in selecting girls (thirteen of fourteen pregnancies) and a slightly lower rate of success in those desiring male fetuses. One obvious benefit of this procedure is that it enables parents to avoid having children with sex-linked or X-linked diseases,... simply by selecting female offspring. Among the troubling aspects of this new technique is a strong preference in some cultures for male offspring and the social disruptions this may engender.”⁸³ Pre-implantation screening further limits the possibility of post-implantation screening in ART treatment.

Under either scenario, serious ethical questions are raised by the ability of prospective parents to engineer their potential children. It may become more tolerable if gender selection is made at the time of fertilization by selecting gametes with the chromosomes for a particular gender, rather than after an embryo has successfully been implanted and a fetus is thriving. However, this does not eliminate the ethical problems raised by gender selection.

iv. Maternal Age. As technology improves, and more women rely on donated eggs, women are able to bear children much later in life than ever before. “[O]nce a woman celebrates her 42nd birthday, the chances of her having a baby using her own eggs, even with advanced medical help, are less than 10%. At age 40, half of her eggs are chromosomally abnormal; by 42, that figure is 90%.”⁸⁴ Older women fare better using donated eggs, and as a result, older patients are turning to donation as a way to overcome fertility problems.⁸⁵ Donor eggs were used in approximately 10% of all ART cycles in 1999, constituting 9,066 cycles.⁸⁶

⁸³Havins, *supra* note 80, at 842-43.

⁸⁴Nancy Gibbs, *Making Time For A Baby; For years, women have been told they could wait until 40 or later to have babies. But a new book argues that's way too late.* TIME, Apr. 15, 2002, 48.

⁸⁵CDC report, *supra* note 13, at 42. “Among women older than age 46, more than 70% of all ART cycles used donor eggs.”

⁸⁶*Id.*

The National Center for Health Statistics reported that in 1999, 174 women in their fifties gave birth to children.⁸⁷ “The number of births to women aged 45-54 rose to 4,565 in 2000... this is the highest number recorded for that age group in more than three decades, according to the Centers for Disease Control and Prevention, and that’s due at least in part to fertility-enhancing therapies.”⁸⁸ To the extent that this medical possibility is indeed achievable, it raises important ethical questions for individuals and society at large. The propriety of delayed motherhood is a substantial question that merits research and debate; resolution of the ethical question may pit the individual procreative rights of women against society’s interest in children’s welfare.

The availability of fertility technologies enables previously infertile older women to give birth to infants. This raises a host of practical and ethical concerns that society may want to address. The ability to legally restrict the use of fertility procedures is probably limited,⁸⁹ but the fertility industry and society at large should consider the consequences of the use of these technologies by older women. There are a few main objections that typically arise in the context of older motherhood. “Perhaps the easiest and most common argument proffered is that prolonging fertility beyond the body’s biological length of time is considered unnatural and even immoral.”⁹⁰ Other arguments against older motherhood include the probability of the child’s early orphanage and the mother’s lack of physical stamina.⁹¹ Lord Robert Winston, a leading British obstetrician and gynecologist and Professor of Fertility Studies at Hammersmith Hospital in London, argues that “[c]hildren should reasonably expect that their parents should be young enough to play football in the park with them , or to have the energy to indulge in the pursuits which are all part of growing up with their

⁸⁷Editorial, *Assisted Reproduction Questions Posed: Ethical issues remain as technology pushes frontiers of fertility therapies*, BALT. SUN, July 19, 2001, at 16A.

⁸⁸Rhonda Schafner, *Older women seek pregnancy*, TIMES UNION ALBANY, Feb. 10, 2002 (2002 WL 8890364).

⁸⁹*See generally* Jayson, *supra* note 22, at 294-98 (detailing constitutional and legal arguments that women will likely be able to challenge any government-imposed age-based limitations on access to reproductive technologies). A definitive resolution of this issue is beyond the scope of this paper, but as a matter of policy it is probably better to rely on industry standards.

⁹⁰*Id.* at 328.

⁹¹*Id.* at 308.

family.”⁹² Others argue that age-related infertility is part of a woman’s natural life cycle and think that enabling fertility after the time of menopause subverts a natural biological event that “debase[s] the value of the menopause.”⁹³

IV.

The federal government has not been very active in regulating the fertility industry. Prior to 1993, the National Institutes of Health (NIH) were forbidden from funding research involving IVF.⁹⁴ The politics of federal involvement in fertility research and regulation go back to the early 1970s, and are intimately tied to abortion politics. Beginning in 1975 the Department of Health, Education and Welfare (now the Department of Health and Human Services), issued a policy regulation funding of all IVF research. The regulation stated that “[n]o application or proposal involving human in vitro fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.”⁹⁵ As Keith Byers points out, the first application was submitted shortly after the policy was established, and it was approved by NIH in 1978. However, the Ethics Advisory board, established after the birth of the first “test-tube” baby, Louise Brown, rejected the request for funding. Because “the climate of rejection was so resounding,” no IVF research proposals were submitted for ten years.⁹⁶ The Ethics Advisory Board expired in 1980, and has never been reinstituted, creating “a de facto ban on the federal funding of human embryo research,

⁹² *Id.*

⁹³ *Id.* (quoting Lord Winston).

⁹⁴ Byers, *supra* note 9, at 290.

⁹⁵ *Id.* at 290, *referring to* 45 C.F.R. § 46.204(d); 40 Fed. Reg. 33, 527 (1975).

⁹⁶ *Id.* at 291.

including IVF and other assisted reproduction techniques...”⁹⁷ It was not until President Clinton called on the NIH to propose guidelines for IVF research that the federal government contemplated entry into this area.⁹⁸ Congress, however, was much less enthusiastic about federal involvement in any aspect of the ART industry; “Congress responded by refusing to authorize any 1996 or 1997 funds for NIH-sponsored research involving human embryos.”⁹⁹ This political refusal to confront ART squarely has left the industry largely on its own as it continues to push the limits of science in the quest to create human life.

Of the major consequences described above, the most obvious areas for federal government response are consumer protection and assuring the safety and effectiveness of ART procedures. In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act.¹⁰⁰ This act is an important step toward increasing the protection afforded consumers of fertility services, by helping to facilitate the collection and compilation of comparable data by the Centers for Disease Control and Prevention. In addition to requiring reporting clinic success rates, it also developed model certification procedures for IVF clinics.

The FDA is in the process of addressing gap in regulatory oversight of the fertility industry through rule-making that requires screening for infectious disease as well as information gathering about the industry and its practices. These regulations tangentially address some of the consumer protection concerns for recipients, but do nothing to protect donors from exploitation. Left unresolved are the serious ethical consequences of the fertility industry. This is primarily because the FDA is not the proper organization or entity to deal with ethical and political concerns. Indeed, action by the FDA that strayed from its mission to protect the health and safety of the United States would seem to be overreaching. However, we are left with the pressing need for some resolution of these critical ethical questions. Many are loathe to address these issues because of the radioactivity of the abortion debate and the perception that any discussion of embryo status, selective

⁹⁷*Id.*

⁹⁸*Id.* at 292 (citing Gorman, *Brave New Embryos: U.S. Rules for Studies of Early Development are Sure to Stir up a Storm*, TIME, Aug. 29, 1994, at 60).

⁹⁹Byers, *supra* note 9, at 292.

¹⁰⁰42 U.S.C.A. §§ 201, 263a-1–263a-7 (Supp. 1996).

reduction, non-therapeutic genetic screening, or age restrictions on the use of ART, necessarily treads too closely to the politics of abortion.

However, there is much that the federal government can and should do to address and resolve some of these important ethical problems. Despite the FDA's institutional incompetence to resolve some of these ethical issues, there are a variety of steps that can be taken by the FDA and other federal agencies, as well as lawmakers, and industry to try and bring some order to the ethical chaos that surrounds the ART industry.

A. Can the federal government protect consumers of fertility services from deception or confusion?

The 1992 Fertility Clinic Success Rate and Certification Act addresses the vulnerability of infertile couples to manipulation by financially-interested clinics. Though the legislation does not protect consumers from all possible abuses, it greatly helps to provide useful comparable information on the success rates of clinics. The reporting requirement is backed by little supporting regulation, and is contingent on allocations from HHS' annual budget in order to be effective.¹⁰¹ Though it does not extend protection as far as many would like, it is a step in the right direction. Protection of couples seeking fertility treatment is vital because, as fertility decreases with age, "receiving time-consuming treatment from a physician without the proper training in reproductive endocrinology and infertility can directly impact a couple's chances for success."¹⁰²

Some commentators also think that the federal and/or state governments need to establish ways to protect consumers from other unscrupulous techniques or abuses by fertility clinics. While the tort system is available to redress wrongs, "the goal of IVF regulation would be to reduce the likelihood of consumers having

¹⁰¹Byers, *supra* note 9, at 294.

¹⁰²*Id.* at 305.

to engage in litigation in hopes of seeking redress for damages resulting from care falling below minimally accepted standards.”¹⁰³ Byers argues that “[m]easures to ensure quality control should form the foundation” of regulation of the IVF industry. “Licensing IVF clinics would be one of the most effective means to protect consumers.”¹⁰⁴ Furthermore, mandatory audits and on-site compliance visits to fertility clinics can add protection for consumers.¹⁰⁵

B.

Can the government ensure the safety of human cells and tissue used in ART?

The Food & Drug Administration has recently asserted its jurisdiction over human cells, tissues, and cellular and tissue-based products (HCT/P's). In March 2001, Kathryn Zoon, Director of the FDA's Center for Biologics Evaluation and Research (CBER) informed a congressional subcommittee that the FDA has authority to regulate cloning technology under the “biologics provisions of the Public Health Service (PHS) Act and the drug and device provisions of the Federal Food, Drug and Cosmetic (FD&C) Act.”¹⁰⁶ Despite her statements that because of the “profound moral, ethical, and scientific issues, the Administration is unequivocally opposed to the cloning of human beings,” her subsequent comments indicated that “resolution of the Agency's doubts about safety would fulfill its regulatory responsibilities.”¹⁰⁷ The FDA's reluctance

¹⁰³*Id.* at 303.

¹⁰⁴*Id.* at 305.

¹⁰⁵*Id.*

¹⁰⁶Statement by Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, March 28, 2001, *available at* <http://www.fda.gov/ola/2001/humancloning.html>

¹⁰⁷Richard A. Merrill and Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.

to enter into the moral and political fray swirling around potential regulatory topics has played a role in the lack of regulation of ART in general.

The regulatory approach to cloning illustrates the importance of the political atmosphere in which the FDA frequently must act. In asserting authority over new technologies, the FDA risks overstepping its jurisdictional boundaries and possibly curtailing or preventing political resolution of the issue. In its approach to cloning, “the Agency’s procedural shortcut has deflected public debate about the formulation of societal limits on this promising and provocative technology.”¹⁰⁸ The FDA had initially asserted authority over cloning in 1998, not through rulemaking, but in the form of a “Dear Colleague” letter.¹⁰⁹ Acknowledging the importance of the action in what was otherwise a regulatory void, Richard Merrill writes that “the plausibility and propriety of the FDA’s claim remain important issues because both the Clinton and Bush Administrations and Congress have failed to develop any such strategy. In the absence of targeted legislation, the FDA’s program for regulating clinical studies of new medicines will be the instrument that enables the federal government to oversee research into cloning and cloning-related technologies.”¹¹⁰

The FDA’s asserted authority over ART is derived from its more general authority over human somatic cell therapy and gene therapy products. In 1993, the agency published a notice in the Federal Register that attempted to clarify the FDA’s statutory authority over somatic cell therapy products, because they were biological products under the PHS Act as well as drugs under the FD&C Act.¹¹¹ Accordingly they were subject to IND application procedures and requirements. The agency proposed a comprehensive regulatory approach to cellular and tissue based products in March 1997,¹¹² and issued a final rule in 2001 that codifies

L. & TECH. 85, 106(2001).

¹⁰⁸*Id.* at 89.

¹⁰⁹See Dr. Stuart Nightingale, Dear Colleague Letter About Human Cloning, Oct. 26, 1998, at <http://www.fda.gov/oc/oha/irbletr.html> (the letter asserted FDA jurisdiction over clinical research using cloning technology to create a human being under the PHS Act and the FDCA).

¹¹⁰Merrill, *supra* note 107, at 89.

¹¹¹58 Fed. Reg. 53,248 (proposed October 14, 1993).

¹¹²62 Fed. Reg. 9721 (proposed March 4, 1997).

an entire regulatory approach to HCT/P's and requires establishments to register with the FDA and list their products.¹¹³ All of these regulatory steps were based on the statutory authority of the FDA to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the United States. This authority is provided by § 361 of the PHS Act.¹¹⁴

The regulatory approach that was finalized in January 2001 is a risk-based approach that requires increasing screening and reporting burdens as the dangers of disease transmission increase. Though transmission of disease is a concern for all uses of all cellular or tissue-based products, the FDA believed that the degree of risk vary with the source and use of the product. One major factor is whether the use is autologous¹¹⁵ or allogenic.¹¹⁶ No regulatory requirements are imposed on autologous HCT/P's that are not "more than minimally manipulated"¹¹⁷ before being replaced in the person from whom they were removed. Though donated sperm and egg are by necessity for allogenic use, the FDA excepts HCT/P's that are transferred for reproductive purposes between intimate partners from the requirements that establishments which bank, ship, or process HCT/P's follow specific donor screening and/or donor or product testing procedures. The FDA was criticized for extending its requirements to any reproductive HCT/P's but the FDA defended its extension of the regulatory requirements to reproductive tissues:

Currently, FDA does not have regulations in place to address the infectious disease risk of donating, processing, and storing reproductive cells and tissue. Because there is no registration or listing requirement, we have had no accurate information about the industry. We agree with the GAO that extending regulation to reproductive cells will remedy a significant gap in oversight.¹¹⁸

Even before this new rule became final, the FDA was warning researchers using fetal cellular or tissue

¹¹³66 Fed. Reg. 5447 (issued January 19, 2001).

¹¹⁴42 U.S.C. 264.

¹¹⁵The FDA defines "autologous use" to be cells or tissue removed from and transplanted back into the same person.

¹¹⁶The FDA defines "allogenic use" to be cells or tissues transplanted from one person to another.

¹¹⁷The FDA defines "more-than-minimal manipulation" to be processing that alters the biological or relevant functional characteristics of the cell.

products that the FDA has jurisdiction over such items intended for use in humans, and that the FDA required an IND application for such uses.¹¹⁹ The final rule, as well as numerous notices and proposed rules, were cited in the July 6, 2001 letter to sponsors and researchers explaining the FDA's jurisdiction over HCT/P's used in novel ART treatments.¹²⁰ The federal government thus has asserted its jurisdiction over HCT/P's through formal rulemaking, in order to prevent the transmission of communicable diseases from donors to recipients. While this regulatory scheme is still being developed by the FDA, it is significant that for the first time, the fertility industry is being included in the new approach to tissue and cellular regulation. What is missing is any proposal for protecting the children produced with the aid of these technologies. There are a variety of reasons that regulation does not explicitly consider the possible long-term effects on potential children: the politics of the abortion issue inevitably preclude consideration of fetal welfare; the language of rights and the focus of the fertility industry is on the potential parents – few people in the industry explicitly consider the best interests of children created with the aid of ART; and the short-term demand for pregnancy obscures any long-term concern for children, particularly in an area over which federal regulation has not been exercised.

C. Can the government resolve the numerous ethical problems presented by ART?

It is doubtful that the federal government would choose to weigh in on the ethical and legal status of embryos created and frozen in fertility clinics around the country. However, the federal government may want to create an incentive to donate embryos to infertile couples instead of for research or destruction.

Deciding on a public policy that encourages embryo donation would serve two valuable policies: first, it

¹¹⁹See Kathryn C. Zoon, *Letter to Sponsors, Prospective Sponsors and Researchers*, November 30, 2000.

¹²⁰Letter to Sponsors/Researchers – Human Cells Used In Therapy Involving the Transfer of Genetic Material by Means other than the Union of Gamete Nuclei, July 6, 2001, available at <http://www.fda.gov/cber/ltr/cytotrans070601.htm>

would aid infertile couples who may have financial difficulty obtaining ART services; second, by providing a positive alternative to embryo destruction, it will decrease the need for resolution of the moral and legal status of embryos over which there is disputed control. As described above, states can choose to protect embryos by prohibiting their destruction, or could clarify the consequences of a dispute over embryos.

The problem of multiple fetus pregnancies and selective reduction can be addressed in a variety of ways, but it is unlikely that there will be direct regulation of selective reduction due to the sensitivity of the decision and the current sensitivity to any regulatory act that might implicate the right to abortion established by the Supreme Court. One way to minimize multiple pregnancies resulting from ART is through consumer education and potentially through any possible licensing of fertility clinics. Presumably the states could regulate the number of embryos implanted in any given cycle based on the likely health risks to the mothers. Ultimately, the way to discourage the implantation of more embryos than a woman can or should bring to term is to address the financial incentives which lead doctors and patients to desire to maximize their chances of achieving pregnancy. As addressed above, the cost and inconvenience of ART leads to increased pressure to achieve pregnancy in as few cycles as possible; increasing success rates through improving technologies is one way to limit the number of embryos that seem desirable to implant. Another way is to diminish the costs of the procedures through insurance or some other regulation, thus relieving the financial pressure to over-implant.

It is important to remember that, in spite of any reduction of financial incentives, the intensity of the desire to become pregnancy quickly, coupled with the psychological and biological consequences of a ticking “biological clock” make it likely that couples will always desire to increase the chances of pregnancy in whatever ways are medically possible. This is why the industry must take the lead, perhaps in conjunction with licensing, in setting ethical standards for fertility clinics that restrict the abuse of embryo implantation.

As for regulation or prohibition on non-therapeutic genetic screening, the federal government would face a daunting task. Perhaps extension by analogy from anti-discrimination laws the government could prohibit certain classes of screening, but here again efforts to regulate run headlong into the consequences of the abortion debate. Any protection for fetuses is likely to be seen as a threat to a woman's right to choose; the current state of abortion jurisprudence and politics allows only limited protection for fetuses. Some legislatures are understandably wary of entering the contentious fray over when embryos or fetuses might have individual rights that would include protection from parents that prefer a certain gender, eye color, or other genetic trait. As the ability to genetically screen for myriad characteristics improves, it will likely be employed with ART to "design" children. There should be a dialogue about this eventuality, but governments' current ability to intervene seems politically and legally limited. Once again, industry standards become very important.

As for the final ethical issue examined above, increasing maternal age is a problem that can best be addressed through education. The federal and state governments can try to educate women about their fertility, and the effect that increasing age can have on the ability to bear children. The mandatory reporting requirement will help consumers to understand how dramatically their chances of successful ART decline after age 40. Furthermore, the industry trade associations should also encourage their members to dissuade older women from going down the road of ART, which is likely to be unsuccessful as age increases. Clinics should refuse to treat women over a certain age, to be determined by the industry. Factors to be considered include possible health risks to mother and child, the likelihood of success of ART at the woman's current age, and the long-term life and psychological effects on future children when parents are substantially older than typical child-bearing parents. One option could include pre-ART counseling for women who are past or nearing menopause. The most productive approach remains education of consumers, in the hope that knowledge will discourage decisions by older women to become parents through ART close to, during, or even after

menopause.

V. Conclusion

The fertility industry provides many important services and technologies to couples and individuals seeking to become biological parents. Individuals facing infertility deserve compassion and assistance as they struggle to overcome this hurdle to achieving a lifelong dream. These couples also deserve protection from an industry whose financial incentives may lead to interests that are not symmetrical with its patients and consumers. In an area that is rarely covered by insurance, the market for this particular, very expensive health service is more like a traditional consumer purchase than a medical decision between a patient and doctor. Clinics market themselves aggressively to vulnerable patients who may not have the information or dispassionate skepticism necessary to evaluate their options. In light of the potential for abuse, and the difficulty of comparing options, there needs to be consumer protection in this industry. Gradually the federal government is stepping up to protect these consumers. Consumer protection for donors appears to be less pressing to governmental authorities, though it too raises important questions.

Because ART can dramatically effect the health and safety of the recipients and future children, the federal government has recently included human cells used for reproductive purposes in its new approach to regulation HCT/Ps. The purpose of the new regulatory efforts is to ensure that communicable diseases are not transmitted between donors and recipients of HCT/Ps.

These ever-improving fertility technologies have dramatic ethical consequences that need to be addressed. Resolution of these issues has not yet been possible because of a variety of political and practical roadblocks. As technologies push the boundaries of human life, ethical concerns are implicated. They should be ad-

dressed in a thoughtful and deliberate way that is transparent and responsive.

Infertility is a serious problem for many Americans. It is also the modern frontier of science and ethics, where technology collides with values. The development of the fertility industry has proceeded largely outside the reach of government oversight or regulation. The consequences of these technologies need to be understood and addressed by the society in which they occur, and which they effect.